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## Netherlands

### Biotechnology

## Enforcement and Implications of the EU T&L Legislation

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**Report Highlights:** OAA/The Hague has held a series of meetings with Dutch and Danish government officials as well as contacts in the food and feed sectors. These meetings have focused on enforcement of Traceability and Labeling legislation, and the practical application of EU requirements.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
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[NL]

## Outlook

As national governments look to implement Traceability and Labeling (T&L) rules, development of guidelines for enforcement is proving difficult. Guidance from the European Commission (EC) has been long expected, but has not yet been issued. Nonetheless, both Denmark and The Netherlands are preparing to enforce these regulations beginning on April 18, 2004.

There appears to be greater risk to US exports of feed ingredients (e.g. Corn Gluten Feed or Distillers' Dried Grains) to these markets than for any other product. While dialogue between member states, trade and the European Commission appears to have brought about a solution to the most serious of these risks, this solution has yet to be officially communicated to member states. It appears that the biggest threat to trade comes from insufficient or unclear enforcement guidance from the European Commission. Some trade contacts believe that a lack of guidance has affected forward sales, while improper or inconsistent enforcement might result in tie-ups at port.

## Product Clearance Hurdles

Requirements will vary by product, with substantial differences in control regimes for Food versus Feed products.

## Food

In both The Netherlands and Denmark, controls on the presence of biotech products or their proper labeling, will be exercised through standard control systems. Accuracy of labeling as regards biotech content is not seen as being essentially any different than assuring labeling accuracy and product purity in general.

The biggest concern for food inspection authorities will be in controlling import of products containing non-approved biotech varieties. Important questions still remain about the possible frequency of testing for presence of these non-approved varieties, procedures in the event of a positive test (will additional tests be carried out on same product runs, or will one result justify control actions?) and sanctions. Without guidance from the European Commission, enforcement is likely to be much more strict in Denmark, where officials talk of destroying product runs that test positive for non-approved varieties.

Dutch officials point out that they are in a difficult situation: A number of US-approved biotech varieties that have not been approved by the EU have received a positive safety review from the Dutch scientific advisory body RIKILT.

## Who is responsible for tracing and labeling of food?

From a regulatory point of view, the "operator" (i.e. the first handler in the EU) will be responsible for any violations of labeling or content restrictions. As long as no guidelines are issued on what constitutes an acceptable level of control or documentation, EU importers face a serious disincentive to purchase products that might contain unwanted biotech ingredients.

In the Netherlands, enforcement of labeling and food purity regulations is generally based on systems audits of importers, processors and manufacturers. Systematic product testing is not normally involved, but production/quality control systems are audited with occasional, random, testing to verify product purity and labeling accuracy. Dutch authorities also test

products for purity and labeling accuracy if systems audits lead to doubts about adequacy of quality control, or if complaints are lodged with the food inspectorate.

In Denmark, on the other hand, product-testing plays a more prominent role in control of food quality and purity. Danish food inspection services evaluate different product-types for risk of contamination by prohibited or unwanted substances, and run tests on a wide range of products considered to be at elevated risk for containing such contaminants. Danish authorities have expressed concern at the possibility of food products containing non-approved biotech varieties entering the market. It is unclear, however, what frequency of testing (for biotech events) might be applied to imported food products.

In both countries, however, discovery of EU-approved biotech events (beyond threshold limit of 0.9%) in a food item that is not labeled as including biotech ingredients will lead to penalties consistent with other violations of labeling regulations. Special penalties and procedures will not be established for violations involving approved biotech ingredients.

## Feed

We expect few disputes to arise regarding the proper labeling of feed products in these markets. Feed compounders are perfectly willing to label their products as containing biotech products and most feed shipments are expected to be declared as such. While labeling regulations stipulate that an exact list of all biotech events contained must accompany any product, local officials have stressed that they are unlikely to look for 'other EU-approved events' in a shipment declared to contain biotech inputs.

Of most concern is the likelihood that some percentage of feed products will contain non-approved biotech varieties. In both countries, government officials indicated that they will be very active in testing feed ingredients (e.g. Corn Gluten Feed and Distiller's Dried Grains) for non-approved varieties. While producers of these products have quality control systems in place to keep non-approved varieties out, they are not 100% effective.

The prospect of feed compounders having to halt distribution of a product and recall feed if found to contain trace amounts of non-approved varieties might have put an end to trade in products such as Corn Gluten Feed and Distillers' Dried Grains. However, regulations provide for an exemption on feed inputs to allow for continued import of "products which have been lawfully placed on the market in the Community" (EC 1829/2003 Art. 20.1.(b)) before April 18, 2004.

European Commission and Dutch Government officials have indicated that trade in products such as Corn Gluten Feed should be able to continue uninterrupted; not only being eligible for a three year waiver from "zero tolerance" provisions for non-approved varieties, but also being exempted during the period between application and acceptance for this waiver.

Until this position is officially adopted and communicated to member states and importers, however, there is a possibility that officials in other member states might block these products. As justification, they could cite the fact that no products will have yet been granted a waiver.

Over the longer term, it should be remembered that a waiver would not be granted for any new-to-market biotech varieties that are not EU-approved. Commercialization of new varieties in the US, unless they receive simultaneous EU-approval, could cause future complications for the trade in these products.

**Where are pitfalls likely?**

Given the lack of any EC guidance to member states, the biggest threat to US products comes from the possibility that T&L guidelines could be enforced differently in each member state. Some industry sources expect that local food safety authorities with anti-biotech agendas may try to impose unrealistic product-handling requirements on any firms trying to market unlabeled products.

Exporters should keep in mind that even though a product might clear customs in one country, food safety authorities in any other EU member state will enforce labeling requirements according to their own interpretation of T&L standards.